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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,232	04/18/2005	Orde Levinson	23590	3885

24932 7590 05/09/2006

LAUBSCHER SEVERSON  
1160 SPA RD  
SUITE 2B  
ANNAPOLIS, MD 21403

EXAMINER

ROGERS, KRISTIN D

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/505,232	<b>Applicant(s)</b> LEVINSON, ORDE	
	<b>Examiner</b> Kristin D. Rogers	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: page 12, line 24 of the specification recites "...by an a distance..." The Examiner suggest the Applicant revise specification to recite, "by a distance..."

Appropriate correction is required.

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lofley et al. (WO 90/13280) embodiment of Figure 1 and Figure 14. Lofley et al. shows a urine collection device including a urine receptor a rim 13 defining inlet area 11, an elongate tubular member 12 extending to an open end from receptor outlet aperture 14 with opening formed in the sidewall (near 102 of Figure 1) of the tubular member 12, a coupling means 18 for releasably mounting urine collection container, and a flow

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director 102 (page 13, lines 9-12). In regard to claim 2, Lofley et al. shows the flow director is a projection along the tubular member (Figure 1). In regard to claims 3 and 4, Lofley et al. shows that the projection is provided upstream and downstream of the opening. The Examiner is defining upstream of the opening according to Figure 1 as the region to the right and along wall 16 of 102 and downstream as the region to the left and along wall 19 of 102. In regard to claim 5, Lofley et al. shows the projection upstream the opening as a surface inclined relative to the surface of the side of the tubular member 12 (Figure 1 shows the inclined surface at 102). In regard to claim 6, Lofley et al. shows a wall 16 that extends across the tubular member corresponding to the upstream edge of opening. In regard to claim 7, the flow director 102 if formed to channel the urine flow along either side of the aperture (Figure 1). In regard to claim 8, Lofley et al. shows the projection towards the longitudinal axis of the tubular member comprises the passage of the coupling means 18 the passage extending into the tubular member and presenting an area within the tubular member into which urine can enter and flow into the collection container 17 (Figure 1 near 103 and 19). In regard to claim 9, the passage of the coupling means 18 extends into the tubular member by an amount corresponding between 20-60% of the height of the internal dimension of the tubular member 12. The Examiner notes that the passage of the coupling means 18 is the region between the collection container 17 and the tubular member 12 and the height of the tubular member is the vertical distance near 14. In regard to claim 10, Lofley et al. shows a semicircular area wherein the passage extends into the tubular member 12 greater downstream than upstream (Figure 1).

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5. Claims 1, 2, 8, 11-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lofley et al. (WO 90/13280) embodiment of Figure 20A to Figure 20G. In regard to claim 1, Lofley et al. shows a urine sample collection device including a urine receptor 301 having a surface that flares out from outlet aperture 306 to a rim 304 defining a perimeter of an inlet area 303; a generally elongate tubular member 315 having an opening formed in the side thereof 316; a coupling means 308; and a flow director 302 and 305 within the tubular adjacent the opening to direct urine past opening 316. In regard to claim 2, the flow director 302 (dashed lines) comprises a projection towards the longitudinal axis of the tubular member 315. In regard to claim 8, Figure 20A shows the projection 302 toward the longitudinal axis of the tubular member comprises the passage of the coupling means 308, the passage extending into tubular member 315 and presenting an area with the tubular member 315 into which urine can enter the collection container 311. In regard to claim 11, Lofley et al. shows a coupling means 308 with further passage 312 and 309 that meet opening 316 to present an area from which air in the collection container can escape into the tubular member 315. The Examiner notes that the collection container 311 comprises air vents 322, that release air into the coupling member 308. Whereby the coupling member is attached to the opening 316 shared by the urine receptor 301 and the elongate tubular member 315, thus releasing the air from the collection container 311 into the elongate tubular member 315. The Examiner further notes, that the opening 316 includes grooves 307 for releasing air into the elongate tubular member 315 (page 18 line 5 to page 20 line 7). In regard to claim 12, the coupling means 308 extends into the tubular member by an

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amount greater than the first mentioned passage (The Examiner notes that the passage of the coupling means 308 is the region between the collection container 311 when coupled to the urine receptor 301 and the tubular member 315 and the height of the tubular member is the vertical distance near end of 315.). In regard to claims 13 and 14, Lofley et al. teaches that the further opening of passage 312 is an incline facing downstream relative of the tubular member 315. In regard to claim 16, the tubular member tapers to the open end near 14 (Figure 20A). The Examiner is considering the tubular member 315 to be in connection with the urine receptor 301 and tapers to open end near 315 of Figure 20A (page 18, line 23-25).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lofley et al. in view of Gordon (4494581) embodiment of Figure 1. Lofley et al. shows a urine collection device but lacks a covering means. In regard to claim 15, Gordon teaches a covering means 39 for the opening between the container 30 and the tubular member 13 adjacent the opening (Figure 1). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Lofley et al. with a

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covering means as taught by Gordon for the purpose of providing a closure cap adjacent the opening.

8. Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lofley et al. in view of Gordon (4494581) embodiment of Figure 4. Lofley et al. shows a device for urine collection but lacks a flow limiter comprising a valve and a closure member comprising a ball. In regard to claims 17-19, Gordon teaches a device for urine collection including a flow limiter 50 in the form of a movable valve, contained in collection container 54 that expands when a predetermined amount of urine is collected in the container and closes the valve of the container (column 3, lines 9-23). In regard to claims 20-22, Gordon teaches a closure member 51 in the form of a hollow sphere positioned between the upper and lower openings capable of closing the upper opening (Figure 4 column 3 lines 20-32) and possesses a density lower than urine. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Lofley et al. with a flow limiter comprising a valve and a closure member comprising a ball as taught by Gordon since such modification would provide an indicator that a predetermined volume of urine was collected and a closure unit less dense than urine to inhibit further flow of urine into the collection container.

### ***Priority***

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent

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application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 0203993.1 dated February 20, 2002, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The application cited above lacks support for a passage of the coupling means extending into the tubular member by an amount corresponding to between 20 and 60% of the height of the internal dimension of the tubular member or for any amount greater. Accordingly, claims 9 and 12 are not entitled to the benefit of the prior application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDR

  
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